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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,872	04/25/2001	Antonio J. Grillo-Lopez	P 0280609/2000-30-154A	4921

909 7590 07/02/2002

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EXAMINER	
NICKOL, GARY B	
ART UNIT	**PAPER NUMBER**
1642	5

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,872	GRILLO-LOPEZ, ANTONIO J.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims **1-50** are pending in the application and are currently under prosecution.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1, 3-4, 5, 7, drawn to a method of treating a CNS wherein the CNS is LM comprising administering an effective amount of an anti-CD20 antibody in combination with a chemotherapeutic, classified in class 424, subclass 130.1.

2. Claims 1, 5, 7, 9, 11-13, 15, 17-18 drawn to a method of treating a CNS comprising administering Rituximab with methotrexate, classified in class 424, subclass 174.1.

3. Claims 1, 5, 7, 9, 11-13, 19-21 drawn to a method of treating a CNS comprising administering Rituximab wherein the antibody is labeled, classified in class 424, subclass 181.1.

4. Claims 1, 5, 7, 9, 11-13, 22-25, 29-32 drawn to a method of treating a CNS comprising administering an anti-CD20 antibody in combination with an anti-CD-40 antibody, classified in class 424, subclass 178.1.

5. Claims 1, 5, 7, 9, 11-13, 33-35 drawn to a method (and composition) of treating a CNS comprising administering an anti-B cell antibody in combination with an CD20 antibody, classified in class 424, subclass 178.1.

6. Claims 2, 6, 8, 10, 14, 16 drawn to a method to TREAT meningeal relapse comprising administering an anti-CD20 antibody, classified in class 424, subclass 130.1.

7. Claims 2, 6, 8, 10, 14, 16 drawn to a method to PREVENT meningeal relapse comprising administering an anti-CD20 antibody, classified in class 424, subclass 130.1.

8. Claims 26-28 drawn to a method of diagnosing PCNSL comprising detecting localization of label conjugated to anti-CD20 antibody, classified in class 424, subclass 9.1.

9-36 Claims 36-45, drawn to a method of treating a CNS lymphoma comprising administering an antibody that binds to ONE B cell antigen, classified in class 424, subclass 130.1.

(Groups 9-36, are improperly linked to a multitude of distinct antigens which encompass independent groups, not species. Upon election, applicant must choose only ONE antigen from Claim 37 or Claim 45)

37-42 Claims 36, 45-50, as specifically drawn to treating a CNS lymphoma comprising administering an antibody that binds to ONE B cell antigen and further comprises administering a cytokine, classified in Class 424, subclasses 155.1, 180.1.

(Groups 37-42, are improperly linked to a multitude of distinct antigens which encompass independent groups, not species. Upon election, applicant must choose only ONE antigen from Claim 45)

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups 1-42 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Species Election: The following claims comprise species of a broader invention as indicated in the above groups. Any group comprising any claim below is subject to a species election.

Claim 3: primary CNS (PCNSL); leptomeningeal metastasis; Hodgkin's Disease

Claim 4: cytarabine and thiotepa; methotrexate and ^{111}In-diethylenetriamine pentacetic acid

Claims 9-10: Rituximab; IF5

Claims 15-16: methotrexate; CHOP; CHOD cytarabine; leucovorin; thiotepa; vincristine; combinations thereof.

(If applicants elect the species of "combinations thereof"- applicant should specifically indicate- by name- which drug is being combined.)

Claims 20, 27: any ONE of the isotopes listed in Claim 20 or Claim 27

Claim 30: OX-26; B3/25; Tf6/14; OKT-9; L5.1; 5E-9; RI7 217; or T58/30

Claim 32: procarbazine; an omega 3 fatty acid; diacyl glycerol; diacyl phospholipid; lyso-phospholipid; cholesterol; a steroid.

Claim 34: anti-CD19; anti-CD22; anti-CD38; anti-MHCII

Claim 44: any ONE of the chemotherapeutics listed in Claim 44

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
June 29, 2002